

K082583

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

FEB 25 2009

Herbert van Dyk
 Philips Medizin Systeme Boeblingen GmbH
 Hewlett-Packard-Str. 2
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This summary was prepared on Feb 24, 2009.

2. The names of the devices are the Philips Medical Systems MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors, Software Revision G.01.
 Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	\$870.1025, II	DSI	Detector and alarm, arrhythmia
	\$870.1025, II	MLD	Monitor, ST Segment with Alarm
	\$870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	\$870.1100, II	DSJ	Alarm, Blood Pressure
	\$870.1110, II	DSK	Computer, Blood Pressure
	\$870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	\$870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	\$870.1915, II	KRB	Probe, Thermodilution
	\$870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	\$870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	\$870.2340, II	DPS	Electrocardiograph
	\$870.2340, II	MLC	Monitor, ST Segment
	\$870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	\$870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	\$870.2600, I	DRJ	System, Signal Isolation
	\$870.2700, II	DQA	Oximeter
	\$870.2770, II	DSB	Plethysmograph, Impedance
	\$870.2800, II	DSH	Recorder, Magnetic tape, Medical
	\$870.2810, I	DSF	Recorder, Paper Chart
	\$870.2850, II	DRS	Extravascular Blood Pressure Transducer
	\$870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	\$870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency

Device Panel	Classification	ProCode	Description
Anesthesiology Devices	\$868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	\$868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	\$868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	\$868.1880, II	BZC	Data calculator Pulmonary-function
	\$868.2375, II	BZQ	Monitor, Breathing Frequency
	\$868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	\$868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
General Hospital and Personal Use Devices	\$880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological Devices	\$882.1400, II	GWR	Electroencephalograph
	\$882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified devices are substantially equivalent to previously cleared Philips IntelliVue Patient Monitors marketed pursuant to K021778, K030038, K032858, K033444, K033513, K040304, K040357, K041235, K042845, K050762, K051106, K052801, K053522, K060221, K060541, K061052, K061610, K062283, K063315, K062392, K063725, K071426.

4. The modification is the introduction of the new interfacing IntelliBridge EC10 and EC5 modules and the related introduction of software release G.01 for the entire IntelliVue Patient Monitors family, models MP40, MP50, MP60, MP70, MP80, and MP90.

5. Indications for Use:

Device Name: Philips Medical Systems MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors, Software Revision G.01.

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP40, and MP50 are additionally intended for use in transport situations within hospital environments.

Intended Use:

The Philips Medical Systems MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors, Software Revision G.01 are intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The monitors are not intended for home use. They are intended for use by health care professionals.

The new interfacing modules IntelliBridge EC10/EC5 and the modified IntelliVue patient monitors, Software Revision Rev. G.01 do not change the intended use.

6. The modified devices have the same physical, technological and performance characteristics, the same functions, and the same scientific concepts as the legally marketed predicate device.
 7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved at system level regression tests, safety and performance tests, EMC and environmental tests, and testing as required from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue Patient Monitors meet all reliability requirements and performance claims.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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c/o Mr. Herbert van Dyk
Q & R Program Manager
Hewlett-Packard-Str. 2
D-71034 Boeblingen
Germany 71034

FEB 25 2009

Re: K082583
Trade Name: Philips Medical Systems MP40, MP50, MP60, MP70, MP80 and MP90
IntelliVue Patient Monitors, Software Revision G.01
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulation Class: Class II (two)
Product Code: MHX
Dated: January 22, 2009
Received: January 26, 2009

Dear Mr. van Dyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman" with a stylized flourish at the end.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082583

Device Name: Philips MP40, MP50, MP60, MP70, MP80, and MP90
IntelliVue Patient Monitors, Software Revision G.01.

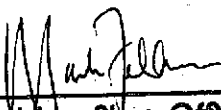
Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP40, and MP50 are additionally intended for use in transport situations within hospital environments.

Prescription Use yes AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use No
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082583